Rev 2: February 2020

FSN Ref: VIG-25-2023-FN01 FSCA Ref: VIG-25-2023-FC01

Date: 2023:07:18

# Field Safety Notice
# Amecath Short Term Haemodialysis Catheter Kit

For Attention of*:1- Albert Schweitzer Ziekenhuis, 2- CATHARINA ZIEKENHUIS, 3- LOCK PHARMA Sp. z.o.o., 4- MAASSTAD ZIEKENHUIS, 5- NOORDWEST ZIEKENHUISGROEP, locatie Alkmaar, 6- STICHTING ZUYDERLAND MEDISCH CENTRUM, 7- UNIV. MED. CENTR. ST. RADBOUD

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
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# Field Safety Notice (FSN)
# Device Commercial Name
# Risk addressed by FSN

| 1. Information on Affected Devices* | |
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| 1. | 1. Device Type(s)* |
| | AMECATH Short Term Haemodialysis Catheter is a soft radiopaque biocompatible polyurethane sterile catheter. The catheters are placed centrally or through femoral vein. Intended Use: Sterile single use device indicated for use in attaining short term access for Haemodialysis or aphaeresis. Supplied Sterile |
| 1. | 2. Commercial name(s)* |
| | AMECATH Short Term Haemodialysis Catheter |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | 6221139DIA-SHT-2aXT |
| 1. | 4. Primary clinical purpose of device(s)* |
| | indicated for use in attaining short term access for Haemodialysis or aphaeresis. Supplied Sterile |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | Victoria XS 14 Fr 25cm equivalent to SDLC-1425-KJU |
| 1. | 6. Software version |
| | NA |
| 1. | 7. Affected serial or lot number range |
| | Lot, 21006, Manufacturing Date: 06/2021, Expiration Date: 05/2024 |
| 1. | 8. Associated devices |
| | NA |

| 2. Reason for Field Safety Corrective Action (FSCA)* | |
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| 2. | 1. Description of the product problem* |
| | Luxation of the catheter due to suture-wing detaching from catheter with lot number 21006 |
| 2. | 2. Hazard giving rise to the FSCA* |
| | Inappropriate Catheter Fixation. Using “Unifix Catheter Tube Fixation Adhesive” instead of wing suturing will prevent the incidence of this problem and has no side effects. |
| 2. | 3. Probability of problem arising |
| | This is the first time to encounter such hazard, so the probability is very low and we did not encounter it with any other user. |
| 2. | 4. Predicted risk to patient/users |
| | Evaluated as Critical and it may cause a harm on the patient |
| 2. | 5. Further information to help characterise the problem |
| | NA |
| 2. | 6. Background on Issue |
| | Manufacturer became aware when the distributor notified us by mail that this incident was reported to the Health Authority. Root cause of the problem is missing the inspection step on the assembly step of the rotating wing over the hub. The containment action is to create FSNs to be circulated to users who received the defect batch, and they will be instructed to use “Unifix Catheter Tube Fixation Adhesive” for catheter fixation instead of rotating wing suturing. In addition, to prevent the incident recurrence, a step will be added in visual |

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| | inspection process to ensure the proper assembly of the rotating wing over the hub and to ensure that the rotating wing is placed after the stopper. |
| 2. | 7. Other information relevant to FSCA |
| | "Unifix Catheter Tube Fixation Adhesive" is already included in all supplied kits |

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| | **3. Type of Action to mitigate the risk*** | |
| **3.** | **1. Action To Be Taken by the User*** | |
| | ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device<br>☐ On-site device modification / inspection<br>☐ Follow patient management recommendations<br>☒ Take note of amendment / reinforcement of Instructions For Use (IFU)<br>☐ Other ☐ None<br>Please use "Unifix Catheter Tube Fixation Adhesive" for catheter fixation instead of suturing rotating wing | |
| 3. | 2. By when should the action be completed? | Within 2 weeks from the date of circulation of this FSN |
| 3. | 3. Particular considerations for: Choose an item.<br>Is follow-up of patients or review of patients' previous results recommended? Choose an item.<br>Provide further details of patient-level follow-up if required or a justification why none is required. | |
| 3. | 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) | Yes |
| **3.** | **5. Action Being Taken by the Manufacturer*** | |
| | ☐ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☒ Other ☐ None<br>FSN will be circulated to users instructing them to use "Unifix Catheter Tube Fixation Adhesive" for catheter fixation instead of suturing the rotating wing. In addition, a step will be added in visual inspection process to ensure the proper assembly of the rotating wing over the hub and to ensure that the rotating wing is placed after the stopper. | |
| 3. | 6. By when should the action be completed? | Within 15 working days. Action is not critical to patient/user safety |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | No |
| 3. | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | |

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| | Choose an item. Choose an item. | |

| 4. General Information* | | |
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| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | Provide reference and date of previous FSN if relevant. |
| 4. | 3. For Updated FSN, key new information as follows: | |
| | Summarise any key difference in devices affected and/or action to be taken. | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | No |
| 4. | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | Eg patient management, device modifications etc. | |
| 4. | 6. Anticipated timescale for follow-up FSN | For provision of updated advice. |
| 4. | 7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Ameco Medical Industries |
| | b. Address | Persoonsgegevens |
| | c. Website address | www.amecathgroup.com |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | NA |
| 4. | 10. Name/Signature | Persoonsgegevens |

| | Transmission of this Field Safety Notice |
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| | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.* |

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.